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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,358	10/30/2001	Richard A. Dixon	SALKINS.017C1	6952

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EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,358	DIXON ET AL.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-33,39-46 and 52-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *20-33,39,40,42-46,52 and 54-59* is/are rejected.

7)☒ Claim(s) *41 and 53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 09/03/04 in reply to the Office action of 06/03/04 has been entered. Claims 20, 31, 39, and 52 have been amended. New claims 56-59 have been added. Therefore, claims 20-33, 39-46 and 52-59 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 112

Claims 20-33, 39-40, 42-46, 52 and 54-55 remain rejected and new claims 56-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification is enabling only for claims limited to a method of producing transformed plant and plant cells having resistance against bacterial diseases as result of expressing SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2 and plants/plant cells/seed produced by said method. This rejection is repeated for the reasons of record as set forth to the Office actions of 08/12/03 and 06/03/04. Applicant's arguments filed 09/03/04 have been fully considered but are not deemed persuasive.

Applicant asserts that the claims are amended to recite a nucleic acid sequence having at least 75% of sequence identity to SEQ ID NO: 1 and encoding a constitutive disease resistance, therefore are enabled when evaluated based on In re Wands factors. Applicant argues that methods for obtaining nucleic acids having at least 75% sequence identity to SEQ ID NO: 1 or nucleic acids that hybridize thereto under the

stringent conditions as recited in the claims, the techniques for generating vectors comprising said nucleic acids, and the techniques for plant transformation are all routine and therefore not undue experimentation. Applicant also argues that the specification provides sufficient guidance, and discloses actual working example.

These arguments are not persuasive. While techniques for generating nucleic acids, vectors comprising said nucleic acids and transformation and regeneration of plants are known, it is not routine in the art to screen for multiple substitutions or multiple modifications as encompassed by the nucleic acids in the instant claimed methods and transgenic plants. One skilled in the art would expect any tolerance to modification for a given DNA/protein to diminish with each further and additional modification or multiple substitutions/ deletions. One skilled in the art would have to make all possible nucleotide modifications in SEQ ID NO: 1 and test all nucleotide sequences that meets the structural limitations to determine which also meet the functional limitation. Applicant has provided no evidence to support the conclusion that the nucleic acids having said structural property (i.e., having at least 75% sequence identity to SEQ ID NO: 1 or nucleic acids that hybridize thereto, or encoding conservative variations of SEQ ID NO:2) would encode a functional constitutive disease resistance polypeptide and would increase disease resistance when expressed in a transgenic plant. Applicant has not provided guidance for functional domains or the regions of the full-length sequence of SEQ ID NO: 1 necessary to encode a functional constitutive disease resistance polypeptide or domains in SEQ ID NO: 2 responsible for the constitutive disease resistance activity. Applicant has not disclosed a transgenic

plant with increased disease resistance as a result of expressing a variant of SEQ ID NO: 1 or 2. The only working example disclosed in the specification employs unmodified SEQ ID NO: 1 and 2.

In Genentech Inc v. Novo Nordisk A/S (42 USPQ2d 1001 at p. 1005). The CAFC stated, "(P)atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable....While every aspect of generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention....[w]hen there is no disclosure of any specific starting material or conditions under which a process can be carried out, undue experimentation is required...." In this case Applicant is expecting others to identify and determine which residues in SEQ ID NO: 1 and 2 would tolerate modifications in order to generate nucleic acid sequences having the structural properties as recited in the claims (75% identity to SEQ ID NO: 1, hybridize thereto, and conservative variations of SEQ ID NO: 2). Applicant is also expecting others to test those modified nucleic acids through the myriad of transgenic plants transformed with each of these modified nucleic acids to identify which would induce increased disease resistance. Under the guidelines set forth in *Genentech*, this constitutes under experimentation.

Therefore, for the reasons stated above and in the last Office actions, the claimed invention is not enabled throughout the broad scope. The rejection is maintained.

Written Description

Claims 20-33, 39-40, 42-46, 52 and 54-55 remain rejected and new claims 56-59 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record as set forth to the Office actions of 08/12/03 and 06/03/04. Applicant's arguments filed 09/03/04 have been fully considered but are not deemed persuasive.

Applicant argues that invention is adequately described given that the claims as amended recite structural and functional limitations. Applicant asserts that one skilled in the art would recognize that inventors has possession of the invention, given that the claimed method and transgenic plants recite nucleic acids having at least 75% sequence identity to SEQ ID NO: 1, nucleic acids that hybridize to SEQ ID NO: 1 under specified hybridization conditions and encoding a constitutive disease resistance.

These arguments are not persuasive because Applicant has not described a representative number of nucleic acids of the genus claimed. Applicant has not described the composition and structure of all nucleic acids having at least 75% identity to SEQ ID NO: 1, all nucleic acids hybridize thereto; encoding a constitutive disease resistance polypeptide, and all nucleic acids encoding conservative variations of SEQ ID NO: 2. The hybridization conditions as recited in the claims define low stringency and no wash time/duration is specified. Unrelated nucleic acids are expected to hybridize under such conditions for a short period of time. Therefore, a substantial variation in

structures and function are expected among the hybridizing nucleic acids. Furthermore, there is no known correlation between the structure and function of constitutive disease resistance genes/polypeptide sequences. Therefore, the disclosure of a method that employs unmodified SEQ ID NO: 1 or nucleotide sequences encoding SEQ ID NO: 2 to enhance disease resistance would not provide adequate written description to methods that employ variants of SEQ ID NO: 1 or 2 as recited in the claims, absent a description of a representative number of nucleic acids of the genus as recited in the claimed methods, transgenic plant/tissue. Therefore, the claimed invention lacks adequate written description. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 56-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryals et al (US 5,614, 395).

The claims are drawn to a method for producing a genetically modified plant having increased disease resistance as compared to its wild-type plant, the method comprising contacting plant cells with a nucleic acid sequence that hybridizes to SEQ ID NO: 1 under hybridization conditions as recited in the claims, said nucleic acid encodes a constitutive disease resistance polypeptide under the control of expression control sequence, producing a plant with increased disease resistance from said plant cells, and transgenic plants with increased resistance as a result of expressing said nucleic acid. Note, the hybridization conditions as recited in the claims do not specify wash time.

Ryals teach a method of producing transformed plants/plant cells having increased resistance against diseases comprising transforming plant cells with a vector comprising nucleic acid sequences encoding pathogen-related (PR) proteins operably linked to promoters including tissue-specific, constitutive and inducible promoters. Ryals et al also teach regeneration of plants from said transformed plant cells and selection of transgenic plants with enhanced resistance against pathogens including *Psuedomonas syringe* and transgenic plants (Examples 109-175). PR proteins provide constitutive disease resistance activity against pathogens including bacterial pathogens (columns 7-8 and 18-20). Given the hybridization conditions as recited in the claims define low stringency and do not specify wash time, the nucleic acid disclosed by Ryals would hybridize to SEQ ID NO: 1 for a short period of time. Therefore, Ryals teaches all claim limitations.

The above rejections can be obviated by amending the claims to replace each of the 75% sequence identity, hybridizing sequence, and nucleic acid encoding conservative variations of SEQ ID NO: 2, with ----SEQ ID NO: 1---, or ----a nucleotide sequence encoding SEQ ID NO: 2---.

Remarks

Claims 20-33, 39-40, 41-46, and 52-55 are free of the prior art because the prior art do not teach or suggest a method of increasing disease resistance in a plant with a nucleic acid having at least 75% sequence identity to SEQ ID NO: 1 and encoding a polypeptide with constitutive disease resistance activity.

Claims 41 and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/24/04
Mai

MEDINA A. IBRAHIM
PATENT EXAMINER